



Alan Kelly, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

22nd December 2021

PQ: 60464/21

To ask the Minister for Health the reason doctors have been prohibited from prescribing Fremanezumab ajovy (details supplied) now that the HSE has taken over the control and distribution of the drug. -Alan Kelly

Dear Deputy Kelly,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 60464/21), which you submitted to the Minister for Health for response.

From 1st October 2021, reimbursement of Fremanezumab, a calcitonin gene-related peptide (CGRP) monoclonal antibody (MAB) is supported under the High Tech Arrangement via a Managed Access Protocol overseen by the HSE-Medicines Management Programme.

Under the Managed Access Protocol, reimbursement of Fremanezumab is supported for the following subgroup of the licensed population:

- prophylaxis of chronic migraine in adults who have failed three or more prophylactic treatments.

The Managed Access Protocol for CGRP MABs, which details the criteria that must be satisfied in order for a patient to be approved for reimbursement of Fremanezumab under the High Tech Arrangement, is available on the website of the HSE-Medicines Management Programme:

<https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/managed-access-protocols/cgrp-mabs/hse-managed-access-protocol-cgrp-mabs.pdf>

Approved prescribers are required to apply for reimbursement approval on an individual basis through the online application system. All reimbursement applications for CGRP MABs submitted are reviewed by the HSE-Medicines Management Programme. When a patient meets the criteria outlined in the Managed Access Protocol, they are approved for reimbursement of a CGRP MAB under the High Tech Arrangement.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Suzanne Doyle', written over a light blue horizontal line.

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service